

SEP 1 0 2001

510(K) Summary of Safety and Effectiveness

K 010618

This 510(K) Summary of Safety and Effectiveness for the Palomar DermoLux™ Pulsed Light System is submitted in accordance with the requirements of Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(K) summary.

Applicant: Palomar Medical Technologies, Inc.

Address: 82 Cambridge St.
Burlington, MA 01803
781-993-2300

Contact Person: Marcy Moore

Telephone: 919-363-2432

Preparation Date: June 6, 2001

Device Trade Name: Palomar DermoLux™ Pulsed Light System

Common Name: Pulsed Light Device

Classification Name: Light-based surgical instrument for use in General and Plastic Surgery and in Dermatology
(see: 21 CFR 878-4810).
Product Code: GEX
Panel: 79

Legally-Marketed Predicate Device: ESC Family of Intense Pulsed Light Systems
PhotoDerm PL, K960772

System Description: The DermoLux™ is a light-based medical device designed for hair removal, treatment of vascular lesions (including leg and facial veins) and treatment of pigmented lesions.

Intended Use of the Device: The DermoLux™ System is intended for the treatment of pigmented and vascular lesions, and hair removal in all skin types.

Performance Data:

The differences in the specifications of the DermoLux™ and the predicate devices do not result in different performance or raise new questions of safety or efficacy.

Conclusion:

Based on the foregoing, the DermoLux™ System is substantially equivalent to the legally-marketed claimed predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2001

Ms. Marcy Moore
Manager of Clinical Studies
Palomar Medical Technologies, Inc.
131 Kelekent Lane
Cary, North Carolina 27511

Re: K010618

Trade/Device Name: DermoLux™

Regulation Number: 878.4810

Regulation Name: Laser surgical instrument for use in general and
plastic surgery and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: June 7, 2001

Received: June 12, 2001

Dear Ms. Moore:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number: K010618

Device Name: DermoLux™

Indications for Use:

The DermoLux™ Pulsed Light system is indicated for the treatment of benign pigmented lesions, including lentigines, nevi, and café-au-lait.


(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(per 21 CFR 801.109)

OR

Over-the-Counter Use


(Division Sign-Off)
Division of General Restorative
and Neurological Devices

510(k) Number K010618